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In the Supreme Court of the United States

OCTOBER TERM, 1949

No. 457

CHESTER WALKER COLGROVE AND COLUSA REMEDY COMPANY (A CORPORATION), PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (R. 88-95) is reported at 176 F. 2d 614.

JURISDICTION

The judgment of the Court of Appeals was entered August 8, 1949 (R. 96), and a petition for rehearing was denied September 19, 1949 (R. 97). On October 17, 1949, by order of the Chief Justice, the time for filing a petition for a writ of certiorari was extended to November 18, and the petition

was filed November 17, 1949. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1). See also Rules 37(b)(2) and 45(a), F.R. Crim. P.

QUESTIONS PRESENTED

1. Whether the evidence supports the judgments of the District Court holding petitioners guilty of contempt.

2. Whether the preliminary and permanent injunctions issued by the District Court are subject to attack in this contempt proceeding.

STATUTES INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, provides in pertinent part:

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is adulterated or misbranded. [21 U.S.C. 331(a).]
>
> Sec. 302. (a) The district courts of the United States * * * shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j). [21 U.S.C. 332(a).]

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387). [21 U.S.C. 332(b).]

Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

(f) Unless its labeling bears (1) adequate directions for use; * * *. [21 U.S.C. 352(f).]

Section 268 of the Judicial Code, 28 U.S.C. (1946 ed.) 385, now 18 U.S.C. (1948 rev.) 401, provided:

The courts of the United States shall have power * * * to punish, by fine or imprisonment, at the discretion of the court, contempts of their authority. Such power to punish contempts shall not be construed to extend to any cases except * * * the disobedience or resistance * * * by any party * * * to any lawful writ, process, order, rule, decree, or command of the said courts.

STATEMENT

The facts in this case are not in dispute. As the opinion of the Court of Appeals points out (R. 89-90), for a number of years petitioner Colgrove has

been engaged in the marketing of drug products represented to be remedies for a number of skin diseases. The products consist of ordinary unrefined petroleum oil and have been shown to be without any therapeutic value (See No. 458, at this Term, C.R. 5-19). The Government instituted numerous libel for condemnation proceedings against these products in all parts of the country on the ground that they were misbranded under Section 502(a) of the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. 352(a) (sometimes hereinafter referred to as "the Act"), in that their labeling contained false and misleading therapeutic claims. Most of these actions resulted in the entry of default decrees of condemnation. (Notices of Judgment under the Federal Food, Drug, and Cosmetics Act, issued by the Federal Security Agency pursuant to 21 U.S.C. 375(a), April 1946, Drugs and Devices No. 1383, and December 1947, Drugs and Devices No. 2087, which together comprise 110 different actions).[1] A group of such consolidated seizure actions was recently tried in the Northern District of Iowa and resulted in a decree of condemnation. *United States* v. *9 Bottles* * * * *"Colusa Natural Oil,"* 78 F. Supp. 721, affirmed *sub nom. Colusa Remedy Co.* v. *United States,* 176 F. 2d 554 (C.A. 8), petition for a writ of certiorari pending, No. 458 at this Term.

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[1] Judicial notice has been taken of such Notices of Judgment. *Libby, McNeill & Libby* v. *United States,* 148 F. 2d 71, 73, fn. 3 (C.A. 2).

In 1942, petitioner Colgrove and the Empire Oil and Gas Company, which he controlled, were prosecuted criminally in the District Court for the Northern District of California. The issue in that case was whether the labeling of the oil was false or misleading in representing it as useful in the treatment of eczema, psoriasis, acne, ringworm, athlete's foot, burns, cuts, poison ivy, and poison oak. After a jury trial, the defendants were convicted. The Court of Appeals for the Ninth Circuit reversed on the ground that a witness produced by the defendants was competent to answer certain questions excluded by the trial court. *Empire Oil & Gas Corp.* v. *United States,* 136 F. 2d 868. Upon remand, the defendants pleaded nolo contendere, and sentences of fine and imprisonment were imposed (R. 89).

In 1945 petitioners resorted to the scheme of failing to mention in the labeling of the oil any of the ailments or diseases for which it was prescribed or recommended (R. 23, 89-90). The representations as to therapeutic claims in the treatment of specified ailments were supplied by extensive newspaper advertising (R. 90). However, under Section 502(f) (1) of the Act, *supra,* p. 3, a drug is deemed misbranded if its labeling fails to bear adequate directions for use. Upon complaint by the Government for injunctive relief, the District Court for the Southern District of California found that this new labeling used by petitioners failed to bear adequate directions for use in the

conditions or diseases for which the oil was prescribed, recommended, and suggested in their advertising. The court issued a preliminary injunction on February 24, 1947, restraining petitioners from shipping "Colusa Natural Oil" or any like product interstate—

> without a label containing specific directions for the use of such product in the treatment of all conditions, ills and diseases for which such product is prescribed, recommended, and suggested, in the advertising material disseminated or sponsored by or on behalf of the defendants or either of them; which directions shall include the quantity of the dose (including quantities for persons of different ages and different physical conditions) to be taken or applied in the treatment of each of such conditions, ills and diseases, as well as the recommended frequency and duration of administration or application of such dosage. [R. 2-3.]

On April 23, 1947, with the written consent of petitioners, the court issued a permanent injunction using the identical language quoted above, except that the words "adequate directions" were substituted for the words "specific directions" (R. 3).

Petitioner Colgrove understood the requirement of the injunction that the labels on the products were required to state the diseases and conditions for which they were recommended in the advertising (see R. 59). A new label was devised, which stated that Colusa Natural Oil was "intended for

use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers" (R. 22).[2] Petitioners then changed their advertising to highlight the same four disease conditions which they listed in their new label, namely, psoriasis, eczema, athlete's foot, and leg ulcers. However, the body of the advertising continued, as before, to give glowing reports of benefits derived in these and eight other conditions. (Pl. Ex. 1, R. 20.) Thus, under the heading, "SUMMARY OF CLINICAL REPORTS ON 28 CASES," there is a quotation of a report allegedly received from a Texas doctor that with this oil he had completely cured patients suffering from psoriasis, eczema, leg ulcers, athlete's foot, poison ivy, and poison oak. Similarly, under the heading, "THOUSANDS OF DOCTORS ARE COLUSA CUSTOMERS—EXCERPTS FROM A FEW OF THEIR REPORTS," there are alleged quotations describing cures of the following diseases: eczema, poison ivy, athlete's foot, leg ulcers, bed sores, burns, psoriasis, acne, ringworm. Under the heading, "EXCERPTS FROM REPORTS BY DRUGGISTS," preceded by the statement, "Druggists in 17 states report 89 stubborn cases where Colusa succeeded after other medicines and doctoring failed," there are reports of cures of eczema, athlete's foot, scaley red face, psoriasis, and acne.

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[2] The condemnation proceedings involved in *Colusa Remedy Co.* v. *United States*, now pending on petition for a writ of certiorari, No. 458 at this Term, arose out of the use of this new label.

The present proceeding arose upon the filing by the United States Attorney in October 1947 of an information in nine counts charging criminal contempt in violating the preliminary and permanent injunctions issued earlier that year. Each count was based upon a different interstate shipment of Colusa Natural Oil which bore the new label recommending the drug for psoriasis, eczema, athlete's foot, and leg ulcers. (R. 2-15.) In conjunction with these shipments, petitioners launched an extensive advertising campaign specifically directing prospective customers to the drug stores that were the consignees of these shipments. (R. 29-32, 59-60). This advertising, summarized above, held out unequivocal promises of benefit not only in the treatment and cure of psoriasis, eczema, athlete's foot and leg ulcers (the diseases mentioned in the new label), but also in the treatment and cure of poison ivy, poison oak, bed sores, burns, acne, ringworm, scaley red face, and itch conditions, none of which were mentioned in the new label. It was alleged that petitioners thereby violated the injunctions in that the labels did not contain directions for use in the treatment of all conditions and diseases for which the product was prescribed, recommended and suggested in the advertising.

Petitioners stipulated that the facts alleged in the information were true, without admitting, however, that their advertising prescribed, recommended and suggested the use of the drug in the treatment of diseases and conditions not mentioned

in the label (R. 24). They also waived a jury trial and special findings of fact under Rule 23(c), F. R. Crim. P. (R. 25). After trial before the court, petitioners were found guilty of criminal contempt as charged in counts 1-8, and not guilty as to count 9 (R. 78-79). Petitioner Colusa Remedy Company was sentenced to pay fines totalling $5000 (R. 34-35). Petitioner Colgrove was sentenced to pay a fine of $1000 on each of counts 3, 5, 7 and 8 and to six months imprisonment in a jail-type institution on each of counts 1, 2, 4 and 6, to run consecutively. Execution of his imprisonment sentences was suspended for a probationary period of five years on condition, among others, that he pay the fines imposed upon him. (R. 36-38.) The judgments were affirmed on appeal (R. 96).

ARGUMENT

The petition proceeds upon the theory that all that was established was a technical violation of an injunction; that there was no proof beyond a reasonable doubt of wilful disobedience. The issue thus asserted is said to relate to the power of the District Court to punish for criminal contempt in the absence of wilful disobedience of the injunction. It is said that the convictions involved a construction of the applicable contempt statute which is in direct conflict with the decisions of this Court.

There is no basis for these claims. In the first place, petitioners rely upon the wrong statute, and, secondly, the record demonstrates that there

was substantial evidence to establish beyond a reasonable doubt deliberate violations of the injunction.

1. Petitioner Colgrove is a law school graduate (R. 65). He has full knowledge and understanding of the injunction, to which he consented. It is clear that he made a thorough study of its terms and understood them. The injunction required that the label of the product contain adequate directions for use in the treatment of all the conditions, ills and diseases for which the product "is prescribed, recommended and suggested." Colgrove testified that he analyzed the injunction and interpreted the language "prescribed, recommended and suggested" as meaning all three, and not "prescribed, recommended *or* suggested," or any one of them. He consulted a standard dictionary and a law dictionary as to the definition of "prescribed." (R. 61-62.) He testified (R. 63):

> I relied upon the common sense conclusion that I was only advertising those diseases that are in the large type; and my literal interpretation of "prescribed, recommended, and suggested," the label not carrying any specific references to those diseases [enumerated in testimonial part of the advertising] and no specific references as to the instructions as to the use for those particular conditions under those names.

In other words, Colgrove reached the conclusion that he was prescribing, recommending and sug-

gesting the drug for the four diseases (psoriasis, athlete's foot, eczema and leg ulcers) mentioned in large type at the top of the advertising, but not for the other diseases and conditions for which the product was held out as a cure by means of the testimonial parts of the advertising. It was also his conclusion that he was not prescribing the oil for any condition when he merely quoted from allegedly scientific reports and letters of satisfied users. Thus, he contends that he acted in good faith and that there is no showing that the violations were wilful.

There is no claim here of mistake, inadvertence, or excusable neglect. Colgrove did that which he deliberately intended to do. He relied upon his own judgment as to the scope of the decree and assumed a calculated risk that the advertisements would not constitute a violation. In making his private determination as to the scope and effect of the injunction, he acted at his peril. It is a well-recognized rule of criminal law that every man is presumed to intend the legitimate consequences of his own act. Wrongful acts knowingly or intentionally committed can neither be justified nor excused on the ground of innocent intent. "The color of the act determines the complexion of the intent." See *Agnew* v. *United States,* 165 U. S. 36, 53. While it is true that no one may be punished for contempt unless the evidence makes it clear that he intended to commit it, this does not mean that a defendant may be heard to say

that he did not intend to defy the authority of the court when he admits that he deliberately committed the act constituting the defiance. Petitioners certainly were not warranted in acting upon their own judgment and in relying upon their own opinion as to the meaning of the decree. Since they made their own decision and accepted the risk of their own judgment in violating the injunction, the violations were wilful ones.[3]

This proceeding was not instituted, as petitioners assume (Pet. 2), under Section 21 of the Clayton Act (28 U.S.C. (1946 ed.) 386, now 18 U.S.C. (1948 rev.) 402), which provides that any person who *wilfully* disobeys any lawful order of any district court, etc., shall be proceeded against for contempt. Section 24 of the Clayton Act (28 U.S.C. (1946 ed.) 389, now 18 U.S.C. (1948 rev.) 402), specifically provided that:

> Nothing herein contained shall be construed to relate to contempts committed * * * in disobedience of any lawful writ, process, order, rule, decree, or command entered in any suit or action brought or prosecuted in the name of, or on behalf of, the United States, but the same, and all other cases of contempt not specifically embraced within section twenty-one of this Act, may be punished in conformity to the usages at law and in equity now prevailing.

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[3] The word "wilful" is employed to characterize a thing done without ground for believing it lawful. *United States* v. *Murdock*, 290 U.S. 389, 394.

Since the injunction suit upon which the contempt proceeding in this case is predicated was instituted in the name of and on behalf of the United States pursuant to the authority of Sections 302(a) and 307 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332(a) and 337), Section 21 of the Clayton Act has no application. See *Hill* v. *United States ex rel. Weiner,* 300 U. S. 105, 107.

This proceeding was instituted under Section 268 of the Judicial Code, 28 U.S.C. (1946 ed.) 385, *supra,* p. 3, under which the courts of the United States are given the power to punish contempts of their authority. Such power extends to the "disobedience or resistance * * * by any party, juror, witness, or other person to any lawful writ, process, order, rule, decree, or command of the said courts." In contrast to Section 21 of the Clayton Act, the word "wilful " nowhere appears in Section 268. Moreover, there are a number of authorities for the proposition that disobedience of a court order, without more, is punishable as contempt, and that the good faith or intent of the defendant may serve only in mitigation of the penalty and not as a defense.[4] In any event, the violations here were wilful.

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[4] High, *Injunctions* (4th ed), Vol. 2, § 1418; *Merrimack River Sav. Bk.* v. *Clay Center,* 219 U. S. 527, 536; *Rodgers* v. *Pitt,* 89 Fed. 424, 429 (C.C. D.Nev.); *In re Braun,* 259 Fed. 309 (C.C. M.D. Pa.); *United States* v. *Sanders,* 290 Fed. 428 (W.D. Tenn.); *Eustace et al.* v. *Lynch,* 80 F. 2d 652 (C.A. 9); *Lustgarten* v. *Felt & Tarrant Mfg. Co.,* 92 F. 2d 277 (C.A. 3).

Complaint is made because the District Court, having found that petitioner Colgrove was technically correct in the literal reading of the injunction, nevertheless based its decision upon the violation of the spirit of the order (R. 77-78). But injunctions are to be honestly and fairly obeyed. The violation of the spirit of an order is considered a breach, even though the strict letter may have been observed. No scheme will be allowed to succeed if its effect constitutes a substantial violation. High, *Injunctions* (4th ed.), Vol. 2, §1446; *Securities and Exchange Commission* v. *Okin,* 137 F. 2d 862 (C.A. 2); *John B. Stetson Co.* v. *Stephen L. Stetson Co.,* 128 F. 2d 981 (C.A. 2).

It is also asserted that the decree was vague and indefinite and that petitioners should not be convicted because of a misunderstanding of its terms. If petitioners were in doubt as to the scope or extent of the injunction, which was entered pursuant to consent, they could have petitioned the District Court for a clarification or construction of the decree. *Regal Knitwear Co.* v. *Labor Board,* 324 U. S. 9, 15.

Petitioners contend that the Government failed to prove that the directions for use on the labels were inadequate. The short answer to this contention is that the labels bore no directions at all for the use of the drug in the conditions referred to in the testimonial part of the advertising, as the injunction fairly required. Furthermore, it was

not intended that they should. As we have shown, Colgrove had determined that the advertising "prescribed, recommended, and suggested" the product as efficacious only in the treatment of the four ailments mentioned at the top of the advertisement, and not for any of the diseases and conditions mentioned in the testimonials in fine print (R. 62). It may be, as petitioners suggest, that directions for use which are adequate in the treatment of eczema would be entirely adequate for the diseases mentioned in the fine print. But the labeling does not so state. One of the remedial purposes of the food and drug legislation is to make self-medication safer. The requirements in Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1)) are designed to effectuate this purpose and to prevent fraud and evasion.

2. It is also asserted that the allegations of the information do not comply with the settled legal requirement for such a pleading. Rule 42(b) of the Federal Rules of Criminal Procedure requires that contempt proceedings be prosecuted upon notice stating the essential facts constituting the criminal contempt charged and describing it as such. The information was designated "Information Re Contempt (Criminal)." It set forth the requirement of the injunction alleged to have been violated and the particulars of each violation. All of the violations were based upon the same charge—that the labels upon petitioners' product, as shipped, violated the decree because they did not contain direc-

tions for use in all of the conditions mentioned in the advertising. No objection to the information was raised at or prior to the trial. Most of the facts alleged were admitted. The sole defense of petitioners was that Colgrove had determined the meaning of the decree; that upon the basis of such determination he had acted in good faith; and that no violation had been intended. That petitioners were fully advised of the ultimate facts underlying the charges is conclusively shown by the defense interposed in the effort to meet them. In the light of all this, it is difficult to appreciate what further allegations the information should have contained in order that petitioners could interpose the defense which they interposed or any other defense. Certainly no substantial prejudice is shown by any alleged defect in the information. Cf. *United States* v. *Mine Workers,* 330 U. S. 258, 295-301.

3. Petitioners seek to attack the convictions upon the ground that "the existence of an independent statutory prerequisite to a conviction for criminal contempt" is not present (Pet. 18). Again, the premise for this contention is the erroneous assumption that this contempt proceeding was instituted under Section 21 of the Clayton Act, which provides for the punishment as contempt of any disobedience of an injunction where "the act or thing so done * * * be of such character as to constitute also a criminal offense" (28 U.S.C. (1946 ed.) 386). As we have shown at pages 12-13,

supra, Section 21 of the Clayton Act does not apply to a proceeding of this character, where the contempt consists of disobedience of a decree entered in a suit brought in the name of the United States. It is also argued that the Federal Food, Drug, and Cosmetic Act does not encompass advertising, and that petitioners have been found guilty of contempt on the basis of statements in their advertisements.

The District Court had jurisdiction of the parties and the subject matter. The injunction suit was instituted pursuant to the authority contained in Section 302 of the Act, *supra,* p. 2, providing that the district courts may enjoin violations of Section 301(a) thereof. The latter section prohibits the introduction into interstate commerce of a misbranded drug, and a violation of the section is made a criminal offense under Section 303 of the Act (21 U.S.C. 333). The District Court was required to determine in the injunction suit that the transactions complained of in that suit violated Section 301(a) before the injunction could be issued. The court determined that the introduction into interstate commerce of the petitioners' product "without a label containing specific directions for the use of such product in the treatment of all conditions, ills and diseases for which such product is prescribed, recommended, and suggested, in the advertising material disseminated or sponsored by or on behalf of the defendants" was a violation of the Act, and enjoined it. No appeal was taken

from the injunction decree. The decree thus determined the criminal character of the acts which it enjoined, and that a violation would be also a criminal offense under the Act. Petitioners having been convicted of disobeying the injunction, now seek to attack collaterally its validity and effect.

It is settled that alleged errors in an injunction "must be corrected by appeal and not by disobedience." *Clarke* v. *Federal Trade Commission,* 128 F. 2d 542, 543 (C.A. 9). In *United States* v. *Mine Workers,* 330 U. S. 258, 293, this Court said that even—

> an order issued by a court with jurisdiction over the subject matter and person must be obeyed by the parties until it is reversed by orderly and proper proceedings. This is true without regard even for the constitutionality of the Act under which the order is issued.

Nevertheless, it should be pointed out in answer to these contentions of petitioners that the violations of the injunction were of such character as to constitute also criminal offenses under the Federal Food, Drug, and Cosmetic Act, so that even if Section 21 of the Clayton Act were applicable, the condition referred to above was satisfied.

It is clear that in enacting the various subsections comprising Section 502 of the Act (21 U.S.C. 352), Congress sought to develop reasonable and effective safeguards for the public in its use of drugs. The

statute is affirmative in its demand that the labeling of a drug bear adequate directions for use, supplying the consumer with information essential to intelligent lay use. It is difficult to conceive of any information which could be more essential to the consumer regarding a drug which he can purchase without a physician's prescription than a statement or enumeration of the disease conditions for which the drug is to be used. Indeed, without such statement or enumeration no directions for the use of such a drug can be considered adequate under the Act. The statutory words "adequate directions for use" cannot be construed *in vacuo,* but must be considered in relation to the information they convey to the lay public and to the efficient administration of the statute. Labeling not only serves to inform the ultimate consumer, but it also performs the vital function of providing a means of determining compliance with, or violation of, the Act. Unless the statutory requirement of adequate directions for use in the labeling is a futility, the directions in the labeling must refer to the use of the drug in specifically enumerated conditions of disease and must lead to the effective use of the drug in the treatment or cure of such specified conditions. Furthermore, where a drug is offered to the public in newspaper advertising for certain disease conditions, it is no imposition upon the legitimate manufacturer to require him to state all of those conditions in the labeling, together with directions ade-

quate for its use in those conditions. The purport of the District Court's interpretation of Section 502(f) (1) of the Act, *supra*, p. 3, and its application to petitioners' methods has received judicial approval in other cases. *United States* v. *150 Packages, etc., Labeled in Part Bush Mulso Tablets, et al.*, 83 F. Supp. 875 (E.D. Mo.); *United States* v. *Various Quantities of "Instant Alberty Food," etc.*, 83 F. Supp. 882 (D.C.).

The undisputed evidence shows, with respect to each violation of the decree of which petitioners were found guilty, that the drug was misbranded because the labeling failed to bear directions for use in the treatment of the ailments which were named in the testimonial part of the advertising. The evidence to support the charges of contempt established violations of Section 301(a), *supra*, p. 2. Since findings were waived (R. 25), there was no requirement that the District Court make a special finding that the acts charged constituted criminal offenses under the Act. As to the asserted power to control advertising, it is obvious from a mere reading of the injunction that it in no way regulates petitioners' advertising. Under the terms of the injunction, petitioners can say whatever they wish in their advertising. The injunction merely requires the label of the product to enumerate all of the disease conditions for which the product is offered in the advertising with adequate directions for use in each of such conditions.

CONCLUSION

The decision below is correct and there is no conflict. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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